

104<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 2290

To amend the medical device provisions of the Federal Food, Drug, and  
Cosmetic Act.

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 8, 1995

Mr. Fox of Pennsylvania introduced the following bill; which was referred to  
the Committee on Commerce

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## A BILL

To amend the medical device provisions of the Federal Food,  
Drug, and Cosmetic Act.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE AND REFERENCE.**

4       (a) SHORT TITLE.—This Act may be cited as the  
5       “Life Extending and Life Saving Device Act of 1995”.

6       (b) REFERENCE.—Whenever in this Act an amend-  
7       ment or repeal is expressed in terms of an amendment  
8       to, or repeal of, a section or other provision, the reference  
9       shall be considered to be made to a section or other provi-

1 sion of the Federal Food, Drug, and Cosmetic Act (21  
2 U.S.C. 201 et seq.).

3 **SEC. 2. DEFINITIONS.**

4 Section 201 (21 U.S.C. 321) is amended—

5 (1) in paragraph (h), by striking “reagent” and  
6 inserting “in vitro diagnostic test system, special  
7 purpose reagent,”, and

8 (2) by adding at the end the following:

9 “(gg) The term ‘special purpose reagent’ means any  
10 monoclonal or polyclonal antibody, antigen, genetic probe,  
11 or other similar or related article that is a component of  
12 an in vitro diagnostic test system.

13 “(hh) The term ‘in vitro diagnostic test system’  
14 means a system intended for use in the diagnosis of dis-  
15 ease or other conditions, including a determination of the  
16 state of health, in order to cure, mitigate, treat, or prevent  
17 disease or its sequelae.”.

18 **SEC. 3. MISSION OF THE FOOD AND DRUG ADMINISTRA-**  
19 **TION.**

20 Section 903 (21 U.S.C. 393) is amended by adding  
21 at the end the following:

22 “(d) The mission of the Food and Drug Administra-  
23 tion (with respect to drugs, biological products, and de-  
24 vices) is to promote and protect the health of the American  
25 people. This mission should be achieved by—

1           “(1) facilitating the timely availability of safe  
2           and effective products that benefit the American  
3           public,

4           “(2) encouraging the efficient development of  
5           new products in the United States,

6           “(3) taking prompt and appropriate action  
7           where postmarketing surveillance demonstrated that  
8           products present a health risk to the American pub-  
9           lic,

10          “(4) ensuring that human drugs, biological  
11          products, and devices are tested and manufactured  
12          consistent with the goal of harmonization of inter-  
13          national standards,

14          “(5) facilitating the flow of information to edu-  
15          cate health professionals and the American public,  
16          and

17          “(6) enforcing the applicable statutes and regu-  
18          lations in a timely, fair, and decisive manner.”.

19   **SEC. 4. HARMONIZATION.**

20          Section 803 (21 U.S.C. 383) is amended by adding  
21   at the end the following:

22          “(c)(1) The Secretary shall take such action as may  
23   be appropriate to harmonize the requirements of this Act  
24   for good manufacturing practice regulations with require-  
25   ments of similar laws in foreign countries through the

1 International Conference on Harmonization by December  
2 1996.

3 “(2) The Secretary shall regularly participate in  
4 meetings with other foreign governments to discuss meth-  
5 ods and approaches to harmonize international regulatory  
6 requirements. The office shall forward any proposed  
7 agreements resulting from such meetings to the appro-  
8 priate officials in each participating country for consider-  
9 ation in the formulation of agreements to harmonize inter-  
10 national regulatory requirements. The office shall have the  
11 responsibility of ensuring that the process of harmonizing  
12 international regulatory requirements for devices and  
13 drugs is continuous.

14 “(3) The Commissioner shall initially report to com-  
15 mittees of the United States Congress with oversight re-  
16 sponsibilities for the United States Food and Drug Ad-  
17 ministration regarding the efforts and accomplishments of  
18 the office no later than 18 months after the date of enact-  
19 ment of this paragraph. Thereafter, the Commissioner  
20 shall report to such committees biennially.”.

21 **SEC. 5. PREMARKET NOTIFICATION.**

22 (a) Section 510 (21 U.S.C. 360) is amended—

23 (1) in subsection (k), by inserting “excluding  
24 any device classified into class I under section 513  
25 or 520, or any device classified into class II under

1 section 513 or 520, if such class II device has been  
2 exempted from the requirements of this subsection  
3 under paragraph (1),” after “a device intended for  
4 human use”,

5 (2) in subsection (k), by striking “report” and  
6 inserting “have the option of reporting”,

7 (3) in subsection (k), by striking “or any per-  
8 son who is not an employee of the United States,  
9 and who is accredited by the Secretary or the Sec-  
10 retary’s designee to receive and review notifications  
11 required under this subsection and to make rec-  
12 ommendations under subsection 513(f)(1) about  
13 such notifications” after “report to the Secretary”,  
14 and

15 (4) by inserting after subsection (k) the follow-  
16 ing:

17 “(l) Within 3 months after the date of the enactment  
18 of this subsection, the Secretary shall publish a notice in  
19 the Federal Register soliciting from the public the identi-  
20 fication of class II devices that should not be subject to  
21 the notification requirements of subsection (k) because  
22 such notification is unnecessary to ensure public health.  
23 The notice shall provide no more than 30 days for submis-  
24 sion of information to the Secretary, and the Secretary  
25 shall by regulation exempt specified class II devices from

1 notification under subsection (k). The proposal for such  
2 a regulation shall permit 30 days for comment. The Sec-  
3 retary shall publish a final regulation in the Federal Reg-  
4 ister no later than 45 days after the end of the comment  
5 period. If the Secretary fails to promulgate a final regula-  
6 tion 45 days after the end of the comment period, each  
7 class II device proposed for exemption from subsection (k)  
8 shall be deemed to be exempt from that subsection.

9 “(m) The Secretary may not withhold a determina-  
10 tion of the initial classification of a device under section  
11 513(f)(1) for any reason, including that the facility in  
12 which a device may be manufactured is not in compliance  
13 with good manufacturing practice requirements set forth  
14 in regulations promulgated under the authority of section  
15 520(f).”.

16 (b) NOTICE.—Section 513(f) (21 U.S.C. 360c(f)) is  
17 amended by redesignating paragraphs (2) and (3) as para-  
18 graphs (3) and (4), respectively, and by inserting after  
19 paragraph (1) the following:

20 “(2)(A) If the Secretary fails to make a determina-  
21 tion under paragraph (1)(A) within 90 days of receipt of  
22 a notification required by subsection (k), the Secretary  
23 shall send a letter by registered mail to the submitter of  
24 such notification stating that additional time is necessary  
25 to determine the initial classification of the device. Addi-

1 tionally, such letter shall state each reason necessitating  
2 the need for additional time and provide the submitter a  
3 date for completion.

4 “(B) Within 90 days of receiving a notification re-  
5 quired under subsection (k) for devices identified as being  
6 substantially equivalent to a class II device, a person ac-  
7 credited to conduct reviews of such notifications shall  
8 make a determination of initial classification under para-  
9 graph (1)(A) of any such device which was not introduced  
10 or delivered for introduction into interstate commerce for  
11 commercial distribution before the date of enactment of  
12 this section. Such determination of initial classification  
13 shall be final. The accredited person shall immediately, by  
14 registered mail, provide to the submitter of such notifica-  
15 tion an order classifying the device. If the accredited per-  
16 son determines that the device should be classified into  
17 class III, such person shall refer the premarket notifica-  
18 tion submission to the Secretary. The Secretary shall have  
19 30 days to review the submission and issue an order ini-  
20 tially classifying the device. If the Secretary fails to make  
21 a classification decision within 30 days, the Secretary shall  
22 send a letter to the submitter of the notification which  
23 conforms to the requirements of subparagraph (A).

24 “(C) Within 60 days of receiving a notification re-  
25 quired under subsection (k) for a device identified as being

1 substantially equivalent to a class III device, a person ac-  
2 credited to conduct reviews of such notification shall make  
3 a determination of the initial classification under para-  
4 graph (1)(A) of any such device which was not introduced  
5 or delivered for introduction into interstate commerce for  
6 commercial distribution before the date of enactment of  
7 this section, and within such time period submit a rec-  
8 ommendation to the Secretary and to the submitter of the  
9 premarket notification which contains such determination.  
10 The recommendation by such person of initial classifica-  
11 tion of a device shall be binding upon the Secretary, unless  
12 the Secretary within 30 calendar days of receipt of the  
13 recommendation finds that the recommendation is clearly  
14 erroneous, issues an order under this subsection initially  
15 classifying the device and provides, as part of the order,  
16 a detailed explanation of the basis for the finding that the  
17 classification recommendation of the accredited person is  
18 clearly erroneous. If within 90 days from the date of re-  
19 ceipt of the notification the Secretary does not issue an  
20 order that differs from the recommendation of the accred-  
21 ited person, the Secretary shall promptly send by reg-  
22 istered mail to the submitter of the notification such rec-  
23 ommendation as the Secretary's order of initial classifica-  
24 tion. If the Secretary does not provide the submitter such  
25 notification by registered mail as specified herein, the rec-



1 ommendation of classification provided to the submitter  
2 of the premarket notification shall become the Secretary's  
3 order of initial classification of the device. Such classifica-  
4 tion may only be charged pursuant to the procedures spec-  
5 ified in paragraph (3) of this subsection.

6       “(D) Any change or modification to a device initially  
7 classified under this subsection, other than a major change  
8 (including any major modification) in the intended use,  
9 shall not require an additional submission under sub-  
10 section (k) if such change or modification is supported by  
11 appropriate data or information, and the change or modi-  
12 fication can be shown to not adversely affect the safety  
13 or effectiveness of the device which was initially classified  
14 under this subsection. All data or information relied upon  
15 to document that a change to (including any modification  
16 of) such device does not require an additional notification  
17 under subsection (k) shall be made a part of the good  
18 manufacturing practice document file required by regula-  
19 tions promulgated under section 520(f) and shall be main-  
20 tained for a period of time equal to the commercial life  
21 of the device, at a minimum.”.

22       (c) Section 513(i)(1) (21 U.S.C. 360c(i)(1)) is  
23 amended by adding after subparagraph (B) the following:

24       “(C) For the purpose of determining the intended use  
25 of a predicate device under subparagraph (A), each use

1 reasonably included within a general use for the predicate  
2 device shall be deemed a legally marketed use of the predi-  
3 cate device and shall be available in premarket notifica-  
4 tions required under subsection (k).

5 “(D) For the purpose of determining substantial  
6 equivalence, the Secretary shall not consider any uses or  
7 indications of a device that are not specifically identified  
8 in a premarket market notification submission under sub-  
9 section (k).”.

10 **SEC. 6. THE RISK/BENEFIT DETERMINATION.**

11 Section 513(a)(2)(A) is amended by striking the  
12 comma following the word “intended” and adding to the  
13 end of the paragraph the following: “by the person legally  
14 responsible for labeling the device,”.

15 **SEC. 7. EFFECTIVENESS DETERMINATION.**

16 (a) Section 513(a)(3)(A) (21 U.S.C. 360c(a)(3)(A))  
17 is amended by adding at the end the following: “Well-con-  
18 trolled clinical investigations shall not be appropriate, un-  
19 less the Secretary determines, after consultation with an  
20 advisory committee constituted under subsection (b) that  
21 such investigations are necessary to demonstrate that the  
22 device will have the effect it purports or is represented  
23 to have under the conditions of use prescribed, rec-  
24 ommended, or suggested in the labeling of the device. Any  
25 person may submit well-controlled clinical investigations

1 to the Secretary to demonstrate that a device will have  
2 the effect it purports or is represented to have under the  
3 conditions of use prescribed, recommended as suggested  
4 in the labeling of the device, and, without reliance on an  
5 advisory committee, the Secretary may determine that  
6 such studies are appropriate for such purpose.”.

7 (b) Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is  
8 amended by adding at the end the following:

9 “(C) The determination of effectiveness shall not in-  
10 clude any of the following:

11 “(i) The evaluation of clinical outcomes, if the  
12 use of a device provides a medical contribution to  
13 the diagnosis or treatment of the persons for whom  
14 the device is intended, unless the device is rep-  
15 resented in the labeling of the device to provide a  
16 therapeutic effect to the persons for whom the device  
17 is intended.

18 “(ii) The evaluation of relative effectiveness,  
19 unless the performance of a device is compared to  
20 that of another device through labeling or other rep-  
21 resentations by the person legally responsible for the  
22 labeling of the device.

23 “(iii) The evaluation of cost effectiveness rep-  
24 resentations.

1           “(iv) The evaluation of any indication for use  
2           not included in the labeling of a device, unless the  
3           person legally responsible for the labeling of the de-  
4           vice promotes such indications for use.”.

5   **SEC. 8. PREMARKET APPROVAL.**

6           (a) Section 515(c)(1) (21 U.S.C. 360e(c)(1)) is  
7           amended by inserting “, or may file such application with  
8           a person or organization authorized to review applications  
9           for premarket approval” after “class III device” and by  
10          redesignating paragraph (2) as paragraph (4) and by add-  
11          ing after paragraph (1) the following:

12          “(2)(A) Persons or organizations authorized to re-  
13          ceive and review applications for approval of class III de-  
14          vices shall review such applications in accordance with the  
15          schedule of events identified in subsection (d)(2), unless  
16          such organization or person by contract with an applicant  
17          alters the schedule of events or eliminates any such event  
18          other than the requirements to file an application before  
19          undertaking a substantive review, refer an application  
20          under subparagraph (C) to an advisory committee con-  
21          stituted under the authority of section 513(b), and com-  
22          plete the review of an application in a timely manner.

23          “(B) The review standard for a premarket approval  
24          application applicable to such persons or organizations

1 shall be identical in all respects to the standard of review  
2 the Secretary is required to follow under this section.

3 “(C) The scope of review responsibility of such per-  
4 sons or organizations authorized to conduct reviews of pre-  
5 market approval applications shall include—

6 “(i) the filing of applications for substantive re-  
7 view,

8 “(ii) the review of applications to determine  
9 whether there is a reasonable assurance that a de-  
10 vice is safe and effective for its labeled uses,

11 “(iii) the presentation, when appropriate, of  
12 such applications to an advisory committee con-  
13 stituted under section 513(b), and

14 “(iv) the evaluation of advisory committee rec-  
15 ommendations and premarket approval applications  
16 and the formulation of reports and recommendations  
17 to be submitted to the Secretary no later than 30  
18 days after receipt of an advisory committee’s rec-  
19 ommendation.

20 Recommendations to the Secretary shall specify whether  
21 an application should be approved or denied and shall  
22 state the basis for the recommendation.

23 “(D) If an advisory committee is not required to re-  
24 view a premarket approval application, such person or or-  
25 ganization shall no later than 120 days after filing, or at

1 such other designated time determined by the applicant  
2 and the accredited person, provide the Secretary with a  
3 report and recommendation in accordance with the re-  
4 quirements of subparagraph (C).

5       “(E) The Secretary shall approve or deny an applica-  
6 tion reviewed by an accredited person within 180 days of  
7 receipt of an application which has been accepted for filing  
8 under subsection (c), unless the accredited person submits  
9 its report and recommendation to the Secretary later than  
10 150 days after such receipt. If the report and rec-  
11 ommendation of an accredited person is submitted to the  
12 Secretary later than 150 days after receipt of an applica-  
13 tion which has been accepted for filing under subsection  
14 (c), the Secretary shall have 30 days from the date of re-  
15 ceipt to approve or deny the application.

16       “(F) The recommendation of an accredited person to  
17 approve or deny an application shall be binding upon the  
18 Secretary, unless the Secretary finds that such rec-  
19 ommendation is clearly erroneous. In the event that the  
20 Secretary makes such a finding, the Secretary shall pro-  
21 vide a detailed explanation of the basis therefor.

22       “(G) The Secretary shall approve or deny applica-  
23 tions for premarket approval of class III devices pursuant  
24 to the requirements of subsection (d).

1       “(3) The Secretary may use experts qualified by  
2 training and experience in addition to employees of the  
3 United States Government to review applications. Reviews  
4 by such experts may relate to portions of an application  
5 or entire applications. Each such review shall be in writing  
6 and submitted to the Secretary for consideration of wheth-  
7 er to approve a device for commercial distribution.”.

8       (b) Section 515(c) (21 U.S.C. 360e(c)), as amended  
9 by subsection (a), is amended by adding the following at  
10 the end of paragraph (4): “Such panel shall be scheduled  
11 to meet at least 4 times each calendar year to consider  
12 among other things the approval of applications submitted  
13 to the Secretary under this subsection. Such meetings  
14 shall, to the extent possible, be scheduled at equal inter-  
15 vals throughout the year.”.

16       (c) Section 515(d) (21 U.S.C. 360e(d)) is amended  
17 by redesignating paragraphs (2) and (3) as paragraphs  
18 (5) and (6), respectively, and by inserting after paragraph  
19 (1) the following:

20       “(2) Each application received under subsection (c)  
21 shall be reviewed in the following manner to achieve final  
22 action on such applications within 180 days of their re-  
23 ceipt:

24               “(A) The Secretary shall make a determination  
25       within 30 days of receipt of an application submitted

1 under subsection (c) of whether the application sat-  
2 isfies the content requirements of subsection (c)(1)  
3 and applicable regulations.

4 “(B) The Secretary shall meet with an appli-  
5 cant within 90 days of receipt of an application that  
6 has been accepted for filing to discuss the review  
7 status of the application. If the application does not  
8 appear in a form that would necessitate an approval  
9 under this subsection, the Secretary shall, in writing  
10 and prior to the meeting, present to the applicant a  
11 description of any deficiencies with the application  
12 and what information would be necessary to bring  
13 the application into a form that would require an  
14 approval.

15 “(C) The Secretary shall provide an applicant  
16 the opportunity for a meeting 115 days after receipt  
17 of an application which has been accepted for filing  
18 under subsection (c) to inform the applicant of the  
19 status of the application, advise the applicant of any  
20 deficiencies in the application not previously commu-  
21 nicated to the applicant, review proposed labeling for  
22 the device, and review the actions taken to correct  
23 deficiencies identified at the meeting held on the  
24 90th day after receipt of the filed application.



1           “(D) The Secretary shall refer an application to  
2           a panel established under section 513 for review and  
3           for an approval recommendation, unless a panel is  
4           not required under subsection (c)(2), within 30 days  
5           of the meeting referenced in subparagraph (B) or at  
6           the next scheduled panel meeting following such  
7           meeting, whichever is later.

8           “(E) The Secretary shall meet with the appli-  
9           cant within 30 days of the panel review if the Sec-  
10          retary has determined that the application is not in  
11          a form that would require approval under this sub-  
12          section. Prior to the meeting, the Secretary shall, in  
13          writing, present to the applicant each basis for deny-  
14          ing approval of the application and the additional in-  
15          formation necessary to bring the application into a  
16          form that could be approved.

17          “(F) The Secretary shall meet within 10 days  
18          of the panel review to present to an applicant a de-  
19          scription of all additional information necessary to  
20          require an approval of an application under this sub-  
21          section if the Secretary has determined that the ap-  
22          plication appears to be in a form that would receive  
23          approval within 180 days of receipt of such applica-  
24          tion. The applicant may waive such meeting and in-

1       stead receive in writing from the Secretary, within  
2       30 days of the panel review, such information.

3           “(G) The Secretary shall meet with the appli-  
4       cant no later than 150 days after receipt of an ap-  
5       plication which has been accepted for filing under  
6       subsection (c), if an advisory panel is not required  
7       under subsection (c)(2), and inform the applicant  
8       whether or not the application is in a form that  
9       could be approved under this subsection. If the ap-  
10      plication is in such form, the Secretary shall, at or  
11      prior to the meeting, present in writing a description  
12      of all additional information necessary to require an  
13      approval of an application under this subsection. If  
14      the application is not in such form, the Secretary  
15      shall, prior to the meeting, present in writing to the  
16      applicant each basis for denying the approval of the  
17      application and the additional information necessary  
18      to bring the application into a form that could be  
19      approved.

20           “(H) The Secretary shall issue an order either  
21      approving or denying an application within 180 days  
22      of receipt of an application that has been accepted  
23      for filing.

24           “(3)(A) The time for the Secretary’s review of an ap-  
25      plication under this subsection shall not be enlarged by

1 any amendment to the application and shall take no more  
2 than 180 days.

3 “(B) The Secretary shall ensure that each time frame  
4 under paragraph (2) is met. For each instance in which  
5 a review requirement under paragraph (2) is not met, a  
6 report to the Secretary is required no later than 10 days  
7 after the date of the scheduled event set forth in para-  
8 graph (2) fully explaining the reason that the scheduled  
9 time frame was not met. Within 10 days after receipt of  
10 such report, the Secretary shall provide an explanation to  
11 the applicant regarding the failure to comply with para-  
12 graph (2) and set the date for satisfying the scheduled  
13 review program obligation.

14 “(C) On January 1 of each calendar year, the Sec-  
15 retary shall submit to the committees of Congress with  
16 substantive oversight responsibility for the Food and Drug  
17 Administration a report summarizing each instance in the  
18 previous fiscal year in which the requirements of para-  
19 graph (2) were not met. This report shall include reasons  
20 for the failures to meet the requirements of paragraph (2)  
21 and proposals to ensure that such requirements will be  
22 met.

23 “(4) In order to better treat or diagnose life-threaten-  
24 ing or irreversibly debilitating diseases or conditions of

1 man, the Secretary shall promulgate regulations to create  
2 review priority for devices—

3 “(A) representing breakthrough technologies;

4 “(B) for which no approved alternatives exist;

5 “(C) which offer significant advantages over ex-  
6 isting approved alternatives; or

7 “(D) the availability of which is in the best in-  
8 terest of the public health.

9 Such regulations shall include criteria for identifying de-  
10 vices which merit preferential review and shall specify pro-  
11 cedures for implementing such reviews. The Secretary  
12 shall publish in the Federal Register a proposed regulation  
13 no later than 6 months after the date of enactment of the  
14 paragraph, allowing 60 days for comment. The Secretary  
15 shall publish a final regulation no later than 60 days after  
16 the last day of the comment period.”.

17 (d) Section 515(d) (21 U.S.C. 360e(d)) is amended  
18 by adding before the semicolon at the end of paragraph  
19 (5)(B) the following: “(the determination of a reasonable  
20 assurance that a device is effective under the conditions  
21 of use prescribed, recommended, or suggested in proposed  
22 labeling shall not include uses or indications for use not  
23 identified in the application)”.

24 (e) The Secretary of Health and Human Services  
25 shall revise, through notice and comment procedures, the

1 regulations appearing in title 21 of the Code of Federal  
2 Regulations, part 814, to conform the regulations to the  
3 amendments of section 515 of the Federal Food, Drug,  
4 and Cosmetic Act made by this section and to eliminate  
5 premarket approval of supplements which relate to manu-  
6 facturing changes and other changes which do not actually  
7 affect device safety or effectiveness.

8 **SEC. 9. INVESTIGATIONAL DEVICE EXEMPTIONS.**

9 Section 520(g) (21 U.S.C. 360j(g)) is amended by  
10 adding at the end the following:

11 “(6) The Secretary of Health and Human Services  
12 shall, within 120 days of the date of enactment of this  
13 paragraph, by regulation amending the content of parts  
14 812 and 813 of title 21 of the Code of Federal Regula-  
15 tions, update the procedures and conditions under which  
16 devices intended for human use may upon application be  
17 granted an exemption from certain requirements under  
18 the Act. Such regulation shall—

19 “(A) permit the use of investigational devices,  
20 outside of the investigational protocol, in the diag-  
21 nosis or treatment of diseases or conditions that are  
22 life threatening or could be irreversibly debilitating,  
23 when the risk of not using the investigational device  
24 exceeds the probable risk of using such device as de-  
25 termined by the local institutional review board;

1           “(B) require that prior to submitting an appli-  
2           cation to the Secretary, any person intending to in-  
3           vestigate the safety or effectiveness of a class III de-  
4           vice or an implant may submit an investigational  
5           plan, including clinical protocol, to the Secretary for  
6           review; and

7           “(C) provide a submitter who disputes the Sec-  
8           retary’s response under subparagraph (B) a right to  
9           appear before an advisory committee of the inves-  
10          tigational plan and the Secretary’s evaluation of  
11          such plan.

12       Within 30 days of receipt of an investigational plan under  
13       subparagraph (B), the Secretary shall respond in writing  
14       to the submitter identifying each deficiency with the plan  
15       and such other information that will facilitate the review  
16       and approval of an application.”.

17       **SEC. 10. CLASSIFICATION AND RECLASSIFICATION OF IN**  
18                               **VITRO DIAGNOSTIC TEST SYSTEMS.**

19           (a) Section 513 (21 U.S.C. 360c) is amended by add-  
20       ing at the end the following:

21       “INITIAL CLASSIFICATION AND RECLASSIFICATION OF IN  
22                               VITRO DIAGNOSTIC TEST SYSTEMS

23           “(j) Any class III in vitro diagnostic test system in-  
24       tended for human use which was introduced or delivered  
25       for introduction into interstate commerce for commercial  
26       distribution before the date of enactment of this para-

1 graph is deemed to be automatically reclassified by the  
2 Secretary in class II on the date 1 year after the date  
3 of enactment of this subsection unless the Secretary, by  
4 regulation, finds that classification of the device in class  
5 III is necessary to provide reasonable assurance of its  
6 safety and effectiveness. Any such device that the Sec-  
7 retary classifies in class III shall remain in class III for  
8 3 years after the effective date of the regulation classifying  
9 the device in class III. At the end of the 3-year period,  
10 the device is deemed to be automatically reclassified by  
11 the Secretary in class II unless the Secretary, by notice  
12 and comment rulemaking, extends the class III designa-  
13 tion for an additional period of time. Any proposed regula-  
14 tion issued under this subsection finding that a device  
15 shall be classified in class III shall be accompanied by a  
16 full statement of the reasons (and supporting documenta-  
17 tion and data) of the Secretary for finding that classifica-  
18 tion of the device in class III is necessary to provide rea-  
19 sonable assurance of its safety and effectiveness and that  
20 reclassification in class II will not provide such assurance.

21 “CLASSIFICATION

22 “(k) Any in vitro diagnostic test system intended for  
23 human use which is intended to be introduced or delivered  
24 for introduction into interstate commerce for commercial  
25 distribution on or after the date of enactment of this sub-  
26 section is deemed to be classified by the Secretary in class

1 II unless the Secretary, by regulation, finds that classifica-  
2 tion of the device in class III is necessary to provide rea-  
3 sonable assurance of its safety and effectiveness. Any such  
4 device that the Secretary classifies in class III shall re-  
5 main in class III for 3 years after the effective date of  
6 the regulation classifying the device in class III. At the  
7 end of that 3-year period, the device is deemed to be auto-  
8 matically reclassified by the Secretary in class II unless  
9 the Secretary, by notice and comment rulemaking, extends  
10 the class III designation for an additional period of time.  
11 Any proposed regulation issued under this subsection find-  
12 ing that a device shall be classified in class III shall be  
13 accompanied by a full statement of the reasons (and sup-  
14 porting documentation and data) of the Secretary for find-  
15 ing that classification in class II will not provide such as-  
16 surance.”.

17 (b) Section 520(l)(1) (21 U.S.C. 360j(l)(1)) is  
18 amended by adding after “has classified such device in  
19 class I or II” the following: “, except that any device in-  
20 tended for human use described in subparagraphs (A)  
21 through (F) which is an in vitro diagnostic test system  
22 is deemed to be classified by the Secretary in class II on  
23 the date 1 year after the date of enactment of this para-  
24 graph unless the Secretary in response to a petition sub-  
25 mitted under paragraph (2) has classified such device in



1 class I, or the Secretary, by regulation, finds that classi-  
2 fication of the device in class III is necessary to provide  
3 reasonable assurance of its safety and effectiveness. Any  
4 such device that the Secretary classifies in class III shall  
5 remain in class III for 3 years after the effective date of  
6 the regulation classifying the device in class III. Any such  
7 device that the Secretary classifies in class III shall re-  
8 main in class III for 3 years after the effective date of  
9 the regulation classifying the device in class III unless the  
10 Secretary, by notice and comment rulemaking, extends the  
11 class III designation for an additional period of time. At  
12 the end of that 3-year period, the device is deemed to be  
13 automatically reclassified by the Secretary in class II. Any  
14 proposed regulation issued under this paragraph finding  
15 that a device shall be classified in class III shall be accom-  
16 panied by a full statement of the reasons (and supporting  
17 documentation and data) of the Secretary for finding that  
18 classification of the device in class III is necessary to pro-  
19 vide reasonable assurance of its safety and effectiveness  
20 and that reclassification in class II will not provide such  
21 assurance”.

22 **SEC. 11. REGULATION OF SPECIAL PURPOSE REAGENTS.**

23 Section 513 (21 U.S.C. 360c), as amended by section  
24 8, is amended by adding at the end the following:

1 “SPECIAL PURPOSE REAGENTS

2 “(l) Any special purpose reagent is deemed to be clas-  
3 sified by the Secretary in class I, subject to the ‘general  
4 controls’ defined in subsection (h), except the premarket  
5 notification requirement of section 510(k), if—

6 “(1) the labeling complies with all requirements  
7 that the Secretary, by regulation, establishes for in  
8 vitro diagnostic test systems, including a require-  
9 ment that a certificate of analysis provided by the  
10 manufacturer of the special purpose reagent shall be  
11 limited to a description of the physical and chemical  
12 properties of the device, the quantity provided, ap-  
13 propriate storage instruction, expiration date, and  
14 the results of any quality or purity testing conducted  
15 by the manufacturer;

16 “(2) the label for the device bears the statement  
17 ‘For manufacturing or laboratory use only,’; and

18 “(3) distribution of the device is restricted to  
19 laboratories licensed by the Secretary under section  
20 353 of the Public Health Service Act to perform  
21 ‘high complexity’ testing as the Secretary, by regula-  
22 tion, defines.

23 “IN VITRO DIAGNOSTIC TEST SYSTEM

24 “(m) Any laboratory licensed by the Secretary under  
25 section 353 of the Public Health Services Act to perform  
26 ‘high complexity’ testing which uses a special purpose rea-

1 gent to manufacture an in vitro diagnostic test system  
2 only for use in that laboratory shall validate the in vitro  
3 diagnostic test system. The laboratory shall include the  
4 following statement on all labeling and any patent test re-  
5 port: ‘Proprietary assay developed and validated by [name  
6 of laboratory]. The performance characteristics of this  
7 assay have not been cleared or approved by the Food and  
8 Drug Administration’.”.

9 **SEC. 12. AUTHORIZATION OF NONGOVERNMENTAL ORGA-**  
10 **NIZATIONS AND PERSONS TO CONDUCT**  
11 **GOOD MANUFACTURING PRACTICE INSPEC-**  
12 **TIONS AND RESPONSES TO ADVERSE FIND-**  
13 **INGS.**

14 Section 704 (21 U.S.C. 374) is amended—

15 (1) in subsection (a)(1), by inserting “or orga-  
16 nizations and individuals receiving accreditation to  
17 conduct good manufacturing practice inspections  
18 under section 712” after “Secretary”;

19 (2) in subsection (a)(3), by inserting “or an ac-  
20 credited organization or individual under section  
21 712” after “employee”;

22 (3) in subsection (b), by inserting “, or the ac-  
23 credited organization or individual under section  
24 712,” after “employee”;

1           (4) in subsection (b), by inserting “(1)” after  
2       “(b)”, redesignating clauses (1) and (2) as clauses  
3       (A) and (B), respectively, and adding at the end the  
4       following:

5       “(2) The Secretary shall provide at least 10 days  
6       from the date of presentation of the findings in paragraph  
7       (1) for the person receiving such findings to respond. The  
8       Secretary shall take no regulatory action against a person  
9       or article subject to the requirements of the Act until com-  
10      pleting a review of such a response, which is timely sub-  
11      mitted to the Secretary, except the Secretary may take  
12      immediate action when the Secretary finds that there is  
13      a reasonable probability that a device intended for human  
14      use would cause serious, adverse health consequences or  
15      death, or that any regulated article could present an un-  
16      reasonable and substantial risk of injury or illness to the  
17      public health. The Secretary shall provide to the regulated  
18      person, within 30 days of receiving a response to findings  
19      identified in paragraph (1), a detailed assessment of the  
20      response.

21      “(3) At the time an accredited organization or indi-  
22      vidual shall identify in writing each inspectional finding  
23      observed during such inspection which suggests a devi-  
24      ation from requirements under the Act. Within 30 days  
25      from the date of presentation of such findings, the person

1 receiving the findings shall respond in writing to the ac-  
2 credited organization or individual stating the response of  
3 such person to each finding. Within 30 days of receipt of  
4 such response, the accredited organization or individual  
5 shall prepare and submit a written report to the Secretary,  
6 including inspectional findings, the regulated person's re-  
7 sponse to the findings, an assessment of the adequacy of  
8 the response and conclusions, and a copy of the conflict  
9 of interest assessment prepared in accordance with the re-  
10 quirement set forth in section 712(c). Such accredited or-  
11 ganization or individual shall immediately submit to the  
12 Secretary the inspectional findings when the device to  
13 which such findings relate is intended for human use and  
14 presents a reasonable probability that such device would  
15 cause serious, adverse health consequences or death, or  
16 that any regulated article could present an unreasonable  
17 and substantial risk of injury or illness to the public  
18 health.”; and

19 (5) by adding after subsection (e) the following:

20 “(f) Persons duly designated by the Secretary to con-  
21 duct inspections under this section shall not request any  
22 information not permitted under subsections (a) and (e)  
23 unless such person states with specificity and in writing  
24 the identification of the information subject to the request,  
25 the reason for the request, and that the written request

1 seeks to obtain information not required to be produced  
2 under this section.”.

3 **SEC. 13. ACCREDITATION OF NONGOVERNMENTAL ORGANI-**  
4 **ZATIONS OR INDIVIDUALS.**

5 Subchapter A of chapter VII is amended by adding  
6 the following:

7 “ACCREDITATION OF NONGOVERNMENTAL  
8 ORGANIZATIONS OR INDIVIDUALS

9 “SEC. 712. (a) The Secretary shall, within 180 days  
10 after the date of enactment of this section, by regulation  
11 establish procedures and criteria to accredit any organiza-  
12 tion or individuals for purposes of—

13 “(1) conducting good manufacturing practice  
14 inspections authorized under section 704 to deter-  
15 mine the conformance of a facility with regulations  
16 promulgated under section 520(f);

17 “(2) reviewing notifications required under sec-  
18 tion 510(k) and making written recommendations of  
19 initial classification under section 513(f)(1) of de-  
20 vices; and

21 “(3) reviewing applications under section 515(c)  
22 and providing written reviews to the Secretary deter-  
23 mine, within 120 days from the receipt of a submis-  
24 sion requesting accreditation, whether the organiza-  
25 tion or individual submitting such application is fit  
26 to undertake some or all of the activities specifies

1       herein. The Secretary shall notify the applicant in  
2       writing of the Secretary's determination within such  
3       time period.

4       “(b) The Secretary shall take into account the train-  
5       ing and experience of organizations and individuals who  
6       apply for accreditation, including formal education, certifi-  
7       cations, work experience, ability to protect the confiden-  
8       tiality of trade secret and confidential commercial and fi-  
9       nancial information, lack of bias and other related infor-  
10      mation necessary to determine the fitness of an applicant  
11      to undertake activities on behalf of the Department of  
12      Health and Human Services.

13      “(c) Notwithstanding the credentials or qualifications  
14      of any applicant, the Secretary shall, after accreditation  
15      require each person who chooses to use an accredited orga-  
16      nization or individual to determine whether such organiza-  
17      tion or individual has a significant personal or financial  
18      interest in a device, other than compensation for reviews  
19      or inspections, that would influence decisions regarding  
20      such device.”.

21      **SEC. 14. RESEARCH ACTIVITIES.**

22      (a) ACTIVITIES.—Chapter IX, as amended by section  
23      11, is amended by adding after section 906 the following:

24                                   “RESEARCH ACTIVITIES

25                   “SEC. 907. Research activities of the Food and Drug  
26      Administration relating to drugs, devices, and biological

1 products, which are authorized under section  
2 903(b)(2)(D) and section 352 of the Public Health Service  
3 Act, shall directly relate to the review and approval of  
4 drugs, devices, and biological products. In conducting such  
5 research activities, the Food and Drug Administration  
6 may collaborate with the National Institutes of Health,  
7 academic health centers, and other scientific institutions  
8 and the drug and device industry.”.

9 (b) PURPOSE.—Section 903 (21 U.S.C. 393), as  
10 amended by section 3, is amended by adding at the end  
11 the following:

12 “(e) Any research conducted by or for the Food and  
13 Drug Administration shall be solely related directly to (1)  
14 the regulatory mission or (2) professional staff develop-  
15 ment related to that mission and shall be limited to the  
16 minimum necessary to achieve such purposes.”.

17 **SEC. 15. POLICY AND PERFORMANCE REVIEW.**

18 Section 514 (21 U.S.C. 360d) is amended by adding  
19 the following:

20 “(c)(1) The Secretary shall recognize applicable na-  
21 tionally or internationally recognized consensus standards  
22 to determine whether there is a reasonable assurance that  
23 a device is safe or effective or to determine compliance  
24 with any requirement under the Act, except that, any per-  
25 son may elect to submit data other than that required by



1 such standards to demonstrate a reasonable assurance of  
2 device safety or effectiveness or compliance with require-  
3 ments under the Act.

4 “(2) The Secretary in lieu of receiving data dem-  
5 onstrating conformance to standards referenced in para-  
6 graph (1) shall accept certifications from regulated per-  
7 sons that devices conform with each standard identified  
8 in each such certification.

9 “(d) The Secretary shall not rely upon informal agen-  
10 cy statements, including guidance documents, policy state-  
11 ments, points to consider documents, or any other state-  
12 ments intended for a similar purpose, to require any ac-  
13 tion be taken to satisfy a requirement under the Act, un-  
14 less such statement is first subject to the rulemaking pro-  
15 cedure set forth in section 5 U.S.C. e 553.”.

16 **SEC. 16. EXPORT OF NEW DRUGS AND DEVICES.**

17 Section 801(e) (21 U.S.C. 381(e)) is amended—

18 (1) in paragraph (1), by inserting after “under  
19 this Act” the following: “or in violation of section  
20 505 or section 351 of the Public Health Service  
21 Act”,

22 (2) in paragraph (1), by striking the last sen-  
23 tence, and

24 (3) by amending paragraph (2) to read as fol-  
25 lows:

1 “(2) Paragraph (1) does not apply to the export of—

2 “(A) any device—

3 “(i) which does not comply with an appli-  
4 cable requirement under section 514 or 515,

5 “(ii) which under section 520(g) is exempt  
6 from either such section, or

7 “(iii) which is a banned device under sec-  
8 tion 516, or

9 “(B) any drug (including a biological product)  
10 which does not comply with an applicable require-  
11 ment under section 505 or 512 or section 351 of the  
12 Public Health Service Act,

13 unless the device or drug is in compliance with the require-  
14 ments of paragraph (1). In the case of a device or drug  
15 for which an export notice is required under this para-  
16 graph, the Secretary may prohibit the export of such de-  
17 vice or drug if the Secretary determines that the possibil-  
18 ity of the reimportation of the device or drug into the  
19 United States presents an imminent hazard to the public  
20 health and safety of the United States and the only means  
21 of limiting the hazard is to prohibit the export of the de-  
22 vice or drug.”.

23 **SEC. 17. RECLASSIFICATION OF CERTAIN DEVICES.**

24 Section 515 (21 U.S.C. 360e) is amended by adding  
25 at the end the following new subsection:

## 1 “RECLASSIFICATION

2 “(j) The Secretary shall, within 18 months of the  
3 date of enactment of this subsection, publish in the Fed-  
4 eral Register a proposed regulation reclassifying all de-  
5 vices identified in subsection (i)(2) into class II, unless  
6 the Secretary has already published a proposed regulation  
7 required under subsection (i) for each such device. The  
8 Secretary shall provide 60 days for comment on the pro-  
9 posed regulation, and shall publish a final regulation in  
10 the Federal Register within 60 days after the last day for  
11 comment reclassifying into class II each such device not  
12 included in a regulation required under subsection (i), or  
13 maintaining, where appropriate, the original classification  
14 of such devices.”.

15 **SEC. 18. TRACKING.**

16 (a) Section 519(e) is amended to read as follows:

17 “(e) Every person who registers under section 510  
18 and is engaged in the manufacture of a class II or class  
19 III device the failure of which would be reasonably likely  
20 to have life threatening or permanently debilitating health  
21 consequences attributable to the device and which is a per-  
22 manently implantable device, or a life sustaining or life  
23 supporting device used outside a device user facility, or  
24 may designate, shall adopt a method of device tracking.  
25 Manufacturers subject to tracking may satisfy the require-

1 ments of this subsection by relying exclusively on social  
2 security numbers as a method of device tracking.”.

3 (b) The Secretary of Health and Human Services  
4 shall, within 12 months of the date of the enactment of  
5 this Act, revise regulations appearing in part 821 of title  
6 21 of the Code of Federal Regulations, to conform to sec-  
7 tion 519 of the Federal Food, Drug, and Cosmetic Act  
8 as amended by subsection (a).

9 (c) Section 205(c)(2)(C)(vii) (42 U.S.C. e  
10 405(c)(2)(C)(viii)) of the Social Security Act is amended  
11 by redesignating subclauses (II), (III), and (IV) as (III),  
12 (IV), and (V), and inserting after subclause (I) the follow-  
13 ing new subclause:

14 “(II) Section 519(e) of the Federal Food, Drug, and  
15 Cosmetic Act (21 U.S.C. 360i(e)) is exempted from  
16 subclause (I). Social Security account numbers and relat-  
17 ed records obtained or maintained by authorized persons  
18 shall be available for use under section 519(e) of the Fed-  
19 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e))  
20 for purposes of device tracking. The requirements under  
21 section 7(b) of the Privacy Act of 1974 (Public Law No.  
22 93–579, 88 Stat. 1896), shall not apply to any Federal,  
23 State, or local government agency requesting a person to  
24 disclose his/her social security account number for pur-

1 poses of device tracking under section 519(e) of the Fed-  
2 eral Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)).”.

3 **SEC. 19. POSTMARKET SURVEILLANCE.**

4 Section 522 (21 U.S.C. 360l) is amended to read as  
5 follows:

6 “POSTMARKET SURVEILLANCE

7 “SEC. 522. (a) The Secretary may require a manu-  
8 facturer to conduct postmarket surveillance for any device  
9 of the manufacturer first introduced or delivered for intro-  
10 duction into interstate commerce after January 1, 1991,  
11 that is a class III device the failure of which would be  
12 reasonably likely to have life threatening or permanently  
13 debilitating consequences attributable to the device and  
14 which is (1) a permanently implantable device, or (2) a  
15 life sustaining or life supporting device used outside a de-  
16 vice user facility.

17 “(b) Each manufacturer required to conduct a sur-  
18 veillance of a device shall, within 30 days of receiving no-  
19 tice from the Secretary that the manufacturer is required  
20 under this section to conduct such surveillance and sub-  
21 mit, for the approval of the Secretary, a protocol for the  
22 required surveillance. The Secretary, within 60 days of the  
23 receipt of such protocol, shall determine if the principal  
24 investigator proposed to be used in the surveillance has  
25 sufficient qualifications and experience to conduct such  
26 surveillance and if such protocol will result in collection

1 of useful data or other information necessary to protect  
2 the public health and to provide safety and effectiveness  
3 information for the device. The Secretary may not approve  
4 such a protocol until it has been reviewed by an appro-  
5 priately qualified scientific and technical review committee  
6 established by the Secretary.”.

7 **SEC. 20. MISCELLANEOUS.**

8 (a) Chapter III of the Federal Food, Drug, and Cos-  
9 metic Act (21 U.S.C. 355 et seq.) is amended by adding  
10 at the end thereof the following new sections:

11 “DISSEMINATION OF TREATMENT INFORMATION ON  
12 DRUGS AND BIOLOGICAL PRODUCTS

13 “SEC. 311. (a)(1) Notwithstanding sections 301(d),  
14 502(f), 505, and 507 and section 351 of the Public Health  
15 Service Act (42 U.S.C. 262), and subject to the require-  
16 ments of paragraph (2) and subsection (b), a person may  
17 disseminate to any person that is a health care practi-  
18 tioner or other provider of health care goods or services,  
19 a pharmacy benefit manager, a health maintenance orga-  
20 nization or other managed health care organization, or a  
21 health care insurer or governmental agency, written infor-  
22 mation, or an oral or written summary of the written in-  
23 formation, concerning—

24 “(A) a treatment use for an investigational new  
25 drug or an investigational biological product ap-  
26 proved by the Secretary for such treatment use; or

1           “(B) a use (whether or not such use is con-  
2           tained in the official labeling) of a new drug (includ-  
3           ing any antibiotic drug) or a biological product for  
4           which an approval of an application filed under sec-  
5           tion 505(b), 505(j), or 507, or a product license is-  
6           sued under the Public Health Service Act, is in ef-  
7           fect.

8           “(2) A person may disseminate information under  
9           paragraph (1)(B) only if—

10           “(A) the information is an unabridged—

11                   “(i) reprint or copy of a peer-reviewed arti-  
12                   cle from a scientific or medical journal that is  
13                   published by an organization that is independ-  
14                   ent of the pharmaceutical industry; or

15                   “(ii) chapter, authored by an expert or ex-  
16                   perts in the disease to which the use relates,  
17                   from a recognized reference textbook that is  
18                   published by an organization that is independ-  
19                   ent of the pharmaceutical industry;

20           “(B) the text of the information has been ap-  
21           proved by a continuing medical education accrediting  
22           agency that is independent of the pharmaceutical in-  
23           dustry as part of a scientific or medical educational  
24           program approved by such agency;

1           “(C) the information relates to a use that is  
2       recognized under Federal law for purposes of third-  
3       party coverage or reimbursement, and—

4           “(i) the text of the information has been  
5       approved by an organization referred to in such  
6       Federal law; or

7           “(ii) the information is part of a disease  
8       management program or treatment guideline  
9       with respect to such use; or

10          “(D) the information is an accurate and truth-  
11       ful summary of the information described in sub-  
12       paragraph (A), (B), or (C).

13          “(b) In order to afford a full and fair evaluation of  
14       the information described in subsection (a), a person dis-  
15       seminating the information shall include a statement that  
16       discloses—

17           “(1) if applicable, that the use of a new drug  
18       or biological product described in subparagraph (A)  
19       or (B) of subsection (a)(1) and the information with  
20       respect to the use have not been approved by the  
21       Food and Drug Administration;

22           “(2) if applicable, that the information is being  
23       disseminated at the expense of the sponsor of the  
24       drug or biological product;



1           “(3) if applicable, that one or more authors of  
2           the information being disseminated are employees of  
3           or consultants to the sponsor of the drug or biological  
4           product; and

5           “(4) the official labeling for the drug and biological  
6           product, or in the case of a treatment use of  
7           an investigational drug or biological product, the investigator  
8           brochure and all updates thereof.

9           “(c) As used in this section, the term ‘expense’ includes  
10          financial, in-kind, and other contributions provided  
11          for the purpose of disseminating the information described  
12          in subsection (a).

13          “(d) In the case of a professional disagreement between  
14          the Secretary and other qualified experts with respect to the  
15          application of section 502(a), the Secretary  
16          may not use section 502 to prohibit the dissemination of  
17          information in the types of circumstances and under the  
18          conditions set forth in subsections (a) and (b).

19          “DISSEMINATION OF INFORMATION ON DEVICES

20          SEC. 312. (a) Notwithstanding sections 301, 501(f),  
21          501(i), 502(a), 502(f), and 502(o), or any other provision  
22          of law, and subject to subsections (b) and (c), a person  
23          may disseminate to any person that is a health care practitioner  
24          or other provider of health care goods or services,  
25          a pharmacy benefit manager, a health maintenance organization  
26          or other managed health care organization, or a

1 health care insurer or governmental agency, written or  
2 oral information (including information exchanged at sci-  
3 entific and educational meetings, workshops, or dem-  
4 onstrations) relating to a use, whether or not the use is  
5 described in the official labeling, of a device produced by  
6 a manufacturer registered pursuant to section 510.

7 “(b)(1) To the extent practicable, the requirement  
8 with respect to a statement of disclosure under subsection  
9 (b) of section 311 shall apply to the dissemination of writ-  
10 ten and oral information under this section, except that  
11 this paragraph shall not apply to the dissemination of  
12 written or oral information with respect to the intended  
13 use described in the labeling of a device.

14 “(2) A person may disseminate information under  
15 subsection (a) only if—

16 “(A) the information is an unabridged—

17 “(i) reprint or copy of a peer-reviewed arti-  
18 cle from a scientific or medical journal that is  
19 published by an organization that is independ-  
20 ent of the medical device industry; or

21 “(ii) chapter, authored by an expert or ex-  
22 perts in the medical specialty to which the use  
23 relates, from a recognized reference textbook  
24 that is published by an organization that is  
25 independent of the medical device industry;

1           “(B) the information has been approved by a  
2 continuing medical education accrediting agency that  
3 is independent of the medical device industry as part  
4 of a scientific or medical educational program ap-  
5 proved by such agency;

6           “(C) the information relates to a use that is  
7 recognized under Federal law for purposes of third-  
8 party reimbursement, and—

9                 “(i) the text of the information has been  
10 approved by an organization referred to in such  
11 Federal law; or

12                 “(ii) the information is part of a disease  
13 management program or treatment guideline  
14 with respect to such use; or

15           “(D) the oral or written information is—

16                 “(i) part of an exchange of information  
17 solely among health care practitioners, health  
18 care reimbursement officials, and the industry;

19                 “(ii) exchanged for educational or scientific  
20 purposes; and

21                 “(iii) presented at continuing medical edu-  
22 cation programs, seminars, workshops, or dem-  
23 onstrations.

1 “(3) The requirements under subsection (a)(1)(A)  
2 and (B) of section 311 shall not apply with respect to de-  
3 vices.

4 “(c) Notwithstanding section 502(a), 502(f), 502(o),  
5 or any other provision of law, the written or oral dissemi-  
6 nation of information relating to a new use of a device,  
7 in accordance with this section, shall not be construed by  
8 the Secretary as evidence of a new intended use of the  
9 device that is different from the intended use of the device  
10 set forth on the official labeling of the device. Such dis-  
11 semination shall not be considered by the Secretary as la-  
12 beling, adulteration, or misbranding of the device.”.

13 (b) Section 519 (21 U.S.C. 360i) is amended to read  
14 as follows:

15 “RECORDS AND REPORTS ON DEVICES

16 “SEC. 519. (a) Every person who is a manufacturer  
17 or importer, of a device intended for human use shall es-  
18 tablish and maintain such records, make such reports, and  
19 provide such information, as the Secretary may by regula-  
20 tion reasonably require to assure that such device is not  
21 adulterated or misbranded and to otherwise assure its  
22 safety and effectiveness. Regulations prescribed under the  
23 preceding sentence—

24 “(1) shall require a device manufacturer or im-  
25 porter to report to the Secretary whenever the man-  
26 ufacturer or importer receives or otherwise becomes

1       aware of information that reasonably suggests that  
2       one of its marketed devices may have caused or con-  
3       tributed to a death or serious injury;

4               “(2) shall define the term ‘serious injury’ to  
5       mean an injury that—

6                       “(A) is life threatening,

7                       “(B) results in permanent impairment of a  
8       body function or permanent damage to a body  
9       structure, or

10                      “(C) necessitates medical or surgical inter-  
11       vention to preclude permanent impairment of a  
12       body function or permanent damage to a body  
13       structure;

14               “(3) shall require reporting of other significant  
15       adverse device experiences as determined by the Sec-  
16       retary to be necessary to be reported;

17               “(4) shall not impose requirements unduly bur-  
18       densome to a device manufacturer or importer tak-  
19       ing into account his cost of complying with such re-  
20       quirements and the need for the protection of the  
21       public health and the implementation of this Act;

22               “(5) which prescribe the procedure for making  
23       requests for reports or information shall require that  
24       each request made under such regulations for sub-  
25       mission of a report or information to the Secretary

1 state the reason or purpose for such request and  
2 identify to the fullest extent practicable such report  
3 or information;

4 “(6) which require submission of a report or in-  
5 formation to the Secretary shall state the reason or  
6 purpose for the submission of such report or infor-  
7 mation and identify to the fullest extent practicable  
8 such report or information;

9 “(7) may not require that the identity of any  
10 patient be disclosed in records, reports, or informa-  
11 tion required under this subsection unless required  
12 for the medical welfare of an individual, to deter-  
13 mine the safety or effectiveness of a device, or to  
14 verify a record, report, or information submitted  
15 under this Act;

16 “(8) may not require a manufacturer, importer,  
17 or distributor of a class I device to—

18 “(A) maintain for such a device records re-  
19 specting information not in the possession of  
20 the manufacturer or importer, or

21 “(B) to submit for such a device to the  
22 Secretary any report or information—

23 “(i) not in the possession of the man-  
24 ufacturer or importer, or

25 “(ii) on a periodic basis,

1 unless such report or information is necessary to de-  
2 termine if the device should be reclassified or if the  
3 device is adulterated or misbranded; and

4 “(b) Subsection (a) shall not apply to—

5 “(1) any practitioner who is licensed by law to  
6 prescribe or administer devices intended for use in  
7 humans and who manufactures or imports devices  
8 solely for use in the course of his professional prac-  
9 tice;

10 “(2) any person who manufactures or imports  
11 devices intended for use in humans solely for such  
12 person’s use in research or teaching and not for sale  
13 (including any person who uses a device under an  
14 exemption granted under section 520(g)); and

15 “(3) any other class of persons as the Secretary  
16 may by regulation exempt from subsection (a) upon  
17 a finding that compliance with the requirements of  
18 such subsection by such class with respect to a de-  
19 vice is not necessary to (A) assure that a device is  
20 not adulterated or misbranded or (B) otherwise to  
21 assure its safety and effectiveness.

22 “(c) Each manufacturer and importer required to  
23 make reports under subsection (a) shall submit to the Sec-  
24 retary annually a statement certifying that—

1           “(1) the manufacturer or importer did file a  
2           certain number of such reports, or

3           “(2) the manufacturer or importer did not file  
4           any report under subsection (a).

5           “(d) Every person who registers under section 510  
6           and is engaged in the manufacture of—

7           “(1) a device the failure of which would be rea-  
8           sonably likely to have serious adverse health con-  
9           sequences and which is (A) a permanently  
10          implantable device, or (B) a life sustaining or life  
11          supporting device used outside a device user facility,  
12          or

13          “(2) any other device which the Secretary may  
14          designate,

15          shall adopt a method of device tracking.”.

16          (b) Within 120 days after the enactment of this sec-  
17          tion, the Secretary shall delete all regulations in title 21,  
18          part 800 requiring distributors, other than importers, to  
19          make reports of deaths, serious injuries or illness, and  
20          malfunctions related to devices.

21          (c) Section 303(c) (21 U.S.C. 333) is amended by  
22          striking the period at the end of subsection (c) and insert-  
23          ing “; or for having violated 301(a), (b), (c), and (k), by  
24          failure to comply with either subsections 502(t)(2) or  
25          501(h), or having violated subsection 301(g)(1)(B) by fail-



1 ing to furnish material or information required under sub-  
2 section 519(a) if such person acted in good faith, had no  
3 reason to believe that the person's acts violated the law,  
4 and had no prior notice from the Secretary that the acts  
5 constituted violations of the Act.”.

6 (d) Section 201(h) (21 U.S.C. 321(h)) is amended  
7 by striking paragraph (1), and renumbering paragraphs  
8 (2), and (3) as paragraphs (1) and (2), respectively.

9 (e) The Secretary of Health and Human Services  
10 within 120 days of the enactment of this section shall re-  
11 vise all regulations appearing in part 800 of title 21 of  
12 the Code of Federal Regulations to delete any requirement  
13 to report device malfunctions.

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